UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO Master File No. 01-CV-12257-PBS	)	Judge Patti B. Saris

AstraZeneca Pharmaceuticals LP's Individual Surreply in Opposition to Plaintiffs' Motion For Class Certification

[REDACTED VERSION FOR PUBLIC FILING]

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

PRELIMINARY STATEMENT

AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum in further support of its opposition to plaintiffs' motion for class certification. For all of the reasons stated in the Track 1 Defendants' opening brief and expert declarations in opposition to class certification and the Track 1 Defendants' surreply brief and expert declarations, as well as in AstraZeneca's individual memorandum in opposition to class certification (all of which is incorporated herein by reference), none of plaintiffs' proposed classes can be certified under Rule 23.

Plaintiffs' separate reply memorandum with respect to AstraZeneca asserts that AstraZeneca concedes the appropriateness of certification with respect to the Medicare Part B reimbursement of Zoladex. Nothing could be more wrong. As an initial matter, for the reasons set forth in the Track 1 Defendants' submissions, a Medicare Part B co-payor class cannot be certified under the Rule 23 standards. Further, in this case, even a class limited to Zoladex Medicare Part B co-payors fails for the independent reason that there is no adequate class representative with standing to bring such a claim against AstraZeneca.

Below, AstraZeneca demonstrates why plaintiffs cannot proceed on a class basis on behalf of third-party payors or Medicare Part B co-payors for any of the AstraZeneca drugs listed in the AMCC.

ARGUMENT

The Medicare Part B Co-Payor Class Cannot Be Certified

For the reasons set forth in the Track 1 Defendants' submissions in opposition to class certification, liability and causation cannot be determined on a class-wide basis even if the proposed

class were limited to Zoladex Medicare Part B co-payors.[1] In addition, specific factors related to the Medicare reimbursement for Zoladex belie plaintiffs' assertion that common proof of liability and causation is available. At times during the purported class period, regional Medicare administrators independently established different allowed charges for Zoladex. The allowed charge determines both the amount of the Medicare reimbursement and the amount of the patient's co-payment. Thus, co-payments for Zoladex at any given AWP depended on which state the patient was in when he or she received a Zoladex injection and on what basis the local administrator established the allowed amount. The evidence demonstrates that all Medicare administrators did not establish local allowed charges for Zoladex by uniform reference to AWP.

REDACTED

For any given AWP, the allowed charges selected by various regional administrators were not established consistently and were in fact wildly different.

REDACTED

[1] Plaintiffs suggest that it was improper to market the profit available to physicians from discounted acquisition costs below Medicare reimbursement levels but present relevant evidence only with respect to Zoladex. This evidence does not support certification of a class pertaining to other drugs or other distribution channels.

REDACTED

[2] Unless otherwise indicated, all Exhibits are to the Declaration of Jessica V. Barnett in Support of AstraZeneca Pharmaceuticals LP's Individual Surreply in Opposition to Plaintiffs' Motion for Class Certification.

REDACTED

To determine whether AWP had any role in how the administrators set those allowed charges would require a state-by-state investigation.

Furthermore, any proposed class of private payors for Zoladex (which are not subject to Medicare administrators' decisions establishing reimbursement allowances for Zoladex) would likewise not meet the requirements of Rule 23. As in the self-administered context, private payors negotiate independently with physicians to reimburse for Zoladex at an agreed rate, or else simply reimburse at a rate established between the insurance company and the employer who purchased the coverage.

REDACTED

. Thus, determining whether any alleged AWP "fraud" actually caused injury to these private payors would require an individual examination of the basis on which their reimbursement rates were established and their understanding of AWP.

In their reply papers, Plaintiffs rely heavily on the Lupron case in support of their motion for class certification. The Lupron case, however, underscores the impropriety of the proposed AWP-related Medicare Part B class here. In Lupron, the settlement class certified is not defined with

reference to AWP, despite the fact that the complaint was based on an alleged AWP fraud. In re: Lupron Marketing and Sales Practices Litig., 295 F. Supp. 2d 148, 160 (D. Mass. 2003). Instead, the settling parties avoided the difficulties inherent in any attempt to factor in the effect of published AWPs on individual class members in favor of an agreed-upon class having nothing to do with AWP. In re: Lupron Marketing and Sales Practices Litig., 345 F. Supp. 2d 135, 2004 U.S. Dist. LEXIS 23917, *11 (D. Mass.) (settlement class consisted, apart from exclusions, of "All individual persons or entities who, during the Class Period, made Lupron (R) Purchases").

Finally, for the reasons set forth in AstraZeneca's Opposition Memorandum, a Medicare Part B class with respect to Zoladex does not satisfy Rule 23 standards because none of the proposed class representatives is a Medicare Part B co-payor for Zoladex. Thus, none of the proposed class representatives has a claim against AstraZeneca for reimbursements made with respect to Zoladex under Medicare Part B. Accordingly, none of the proposed class representatives has standing, nor do any satisfy the adequacy and typicality requirements of Rule 23 with respect to a class of Medicare Part B Zoladex co-payors.

Plaintiffs erroneously suggest that UFCW is an appropriate class representative of such a Medicare Part B co-payors class. Plaintiffs concede, however, that UFCW never made payments to cover Zoladex Medicare Part B co-payments. Contrary to plaintiffs' assertion, it is *not* "irrelevant" that UFCW did not make payments for Zoladex. It is the law of this case that named plaintiffs do not have standing to bring claims against defendants whose products they did not pay for. In re Pharmaceutical Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 193 (D. Mass. 2003) ("the doctrine of juridical linkage is not indefinitely elastic so as to permit an industry-wide challenge on the basis of the conduct of select companies"); see also Allee v. Medrano, 416 U.S. 802, 828-29 (1974) ("[A] named plaintiff cannot acquire standing to sue by bringing his action on behalf of others who suffered an injury which would have afforded them standing had they been

named plaintiffs. . . . Standing cannot be acquired through the back door of a class action."). Additionally, it is well-settled that named plaintiffs in a purported class action must be members of the class they seek to represent. General Tel. Co. v. Falcon, 457 U.S. 147, 156 (1982) ("a class representative must be part of the class and possess the same interest and suffer the same injury as the class members"). [3]

Therefore, plaintiffs' cited antitrust cases are inapposite, because in an antitrust setting, collusion among defendants is presumed to have a systematic market-wide impact, regardless of who the purchaser is or from which defendant he purchased. It is clear even from the cases cited by plaintiffs that the certification of those classes depended upon this defining characteristic of antitrust claims. In re Aluminum Phosphide Antitrust Litig., 160 F.R.D. 609, 615 (D. Kan. 1995) (plaintiffs paid more "than they would have paid in a truly competitive market"); In re Catfish Antitrust Litig., 826 F. Supp. 1019, 1040 (D. N. Miss. 1993) (each purchaser paid a higher price "than what would have existed in a truly competitive environment"). Plaintiffs' federal, antitrust authority is completely inapposite with respect to plaintiffs' purported class pursuing state-law consumer fraud claims. Indeed, plaintiffs have admitted that liability in this case must be determined on a defendant- and drug-specific basis. (Plaintiffs' Reply To Bristol-Myers Squibb's Individual Memorandum in Opposition to Class Certification). This Court has already agreed that, "in the present case there is no allegation of corporate, contractual, conspiratorial, or other legal connection to establish juridical linkage between all the defendants." In re Pharmaceutical Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 193 (D. Mass. 2003) (finding that named plaintiffs had no standing "with respect to defendants from which no plaintiff has purchased a drug"). Thus,

[3] The only named plaintiff alleged to have made any payments for Zoladex, Teamsters Health & Welfare Fund ("THFW"), also is not a member of the proposed class, because it never covered Medicare Part B co-payments.

UFCW does not have standing is not an adequate representative of a class of Medicare Part B co-payors vis-à-vis AstraZeneca.

The Third Party Payor Classes Cannot Be Certified

For the reasons set forth in the Track 1 Defendants' submissions in opposition to class certification, liability and causation also cannot be determined on a class-wide basis with respect to the third party payor classes. With respect to these claims, plaintiffs completely mischaracterize AstraZeneca's documents. (See also AstraZeneca's Opposition Memorandum at 5-6).

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With respect to all AstraZeneca products, numerous individual issues related to the pricing of, reimbursement for and distribution of these drugs underscore the inappropriateness of class certification, as reflected in the record.

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Similarly, the legitimacy of AstraZeneca's discounts and rebates is not subject to a class-wide determination pursuant to plaintiffs' proposed method of averaging discounts and rebates. Discounts (and rebates) are granted to entities that negotiate with AstraZeneca on behalf of payors, whose market power determines their ability to extract price concessions from AstraZeneca. (See Joint Surreply). The record establishes that the discount or rebate offered to any payor at each point in time is negotiated individually and is subject to a wide range of factors **REDACTED** **REDACTED** (Exh. 7, Alverson Tr. at 59, 94, 108-109, 125-38, 142-44). Negotiations are often carried out on a drug-by-drug basis, and discounts often change over time for a given product, from the time it is launched to the time that it faces generic competition after patent exclusivity has expired. (Id. at 59, 137-138, 142-44).

Because the legitimacy of all of AstraZeneca's pricing and discounting decision for all of its products simply cannot be determined in a single leap, class certification must be denied.

Conclusion

For the reasons set forth above and in AstraZeneca's and the other Track 1 Defendants' submissions in opposition to class certification, Plaintiffs' motion for class certification should be denied.

Dated: Boston, Massachusetts
January 21, 2005

Respectfully Submitted,

By: /s/ Jessica V. Barnett

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CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2005, I caused a true and correct copy of the foregoing AstraZeneca Pharmaceuticals LP's Individual Surreply in Opposition to Plaintiffs' Motion for Class Certification [REDACTED VERSION FOR PUBLIC FILING] and the accompanying Declaration of Monica Lamb to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/ Jessica V. Barnett
Jessica V. Barnett